CANCER SUPPORT COMMUNITY
A Global Network of Education and Hope

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Submitted electronically
RE: Request for Comments: Docket No FDA-2017-N-2732 July 13, 2017 Oncologic Drugs Advisory Committee meeting to discuss biologics license applications 761028 and 761074

On behalf of the Cancer Support Community (CSC) and the patients we represent, we appreciate the opportunity to submit these comments for the July 13, 2017 Oncologic Drugs Advisory Committee meeting to discuss biologics license applications (BLAs) 761028 and 761074.

CSC supports the development of therapies that can improve the lives of people impacted by cancer. We believe that patients deserve access to affordable, high-quality medications that best address their unique needs and preferences. As such, we know that there is a place in the care continuum for biosimilars to provide additional options for patients.

Safety
At the core of the Food and Drug Administration's (FDA or Agency) mission is the responsibility to protect the public health through the safety, effectiveness, quality, and security of drugs, vaccines, and other biological products. As such, CSC expects that the FDA will continue to ensure that biosimilar products are held to the same high standards for safety and clinical efficacy as the originator/reference products. Additionally, CSC expects that the FDA will ensure biosimilar manufacturers are held to the same post-marketing data reporting requirements and physical plant inspections as manufacturers of innovator products.

Efficacy
CSC respects the intent of the FDA to speed development of and approval for biosimilars by utilizing alternative methods of data collection and analysis such as that of indication extrapolation. Given the rapid evolution of data about personalized responses to therapies, CSC encourages the FDA and manufacturers to ensure, through original data and/or post-marketing studies, that the efficacy of biosimilars continue to meet the threshold of the innovator product in each indicated tumor type.

Interchangeability
CSC recognizes the work of the FDA to establish a process for interchangeability. CSC encourages the FDA to require interchangeability thresholds be met for all future biosimilar applications.

Transparency
As the FDA considers the future of all biosimilars, we ask that the Agency work to ensure that there is a high degree of transparency and communication with all stakeholders. Consistent with CSC's belief that patients and their providers should work together, in a shared decision-making model, to determine the best therapy for their unique needs and preferences, decisions about drug switching or substitution should be made at the patient/provider level, not at the pharmacist or payer-mandate level. CSC believes there should be requirements in place to ensure this level of transparency is followed.

Patient Costs
Although outside the scope of the FDA, we feel that it is important to note that an expanded biosimilars market should increase access for patients. This must include affordability measures including patient assistance. In order for patients to benefit from the advances in drug development and the new biosimilar treatment options brought to market there must be adequate financial support/patient assistance from industry.

Conclusion
In closing, we would like to thank the FDA for the opportunity to submit these comments. CSC believes that biosimilars have a role in the patient care continuum. We commend the FDA and the sponsor for working to ensure that marketed biosimilars are as safe and effective as innovator/reference products. CSC stands ready to serve as a resource to the FDA and the sponsor companies as we collectively seek to protect patients while also elevating their voices to inform evolving policy decisions.

Sincerely,

Cancer Support Community

About the Cancer Support Community
As the largest professionally led nonprofit network of cancer support worldwide, the Cancer Support Community (CSC), including its Gilda's Club affiliates, is dedicated to ensuring that all people impacted by cancer are empowered by knowledge, strengthened by action, and sustained by community. CSC achieves its mission through three areas: direct service delivery, research, and advocacy. The organization includes an international network of Affiliates that offer the highest quality social and emotional support for people impacted by cancer, as well as a community of support available online and over the phone. The Research and Training Institute conducts cutting-edge psychosocial, behavioral, and survivorship research. CSC furthers its focus on patient advocacy through its Cancer Policy Institute, informing public policy in Washington, D.C. and across the nation. For more information, please call the toll-free Cancer Support Helpline at 888-793-9355, or visit www.CancerSupportCommunity.org. So that no one faces cancer alone®